UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
BEAUMONT DIVISION

JUDY ROMERO,	§	
	§	
Plaintiff,	§	Civil Action No. 1:03-CV-01367-MAC
	§	
vs.	§	
	§	
WYETH LLC,	§	Honorable Marcia A. Crone
	§	
Defendant.	§	

WYETH'S MOTION FOR SUMMARY JUDGMENT
REGARDING PLAINTIFF'S REMAINING CLAIMS AND BRIEF IN SUPPORT

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I. Introduction and Summary of the Argument

Under Texas law—and in particular the recent decisions in *Lofton v. McNeil Consumer & Specialty Pharm.*, 672 F.3d 372, 373 (5th Cir. 2012) and *Centocor, Inc. v. Hamilton*, No. 10-0223, 2012 Tex. LEXIS 463, 55 Tex. Sup. J. 774 (Tex. June 8, 2012)—the warnings accompanying the FDA-approved hormone therapy medications prescribed to Plaintiff are presumed adequate as a matter of law. Further, under the learned intermediary doctrine—also confirmed by *Centocor*—Wyeth's only duty is to warn Plaintiff's prescribing physician, which it did through the FDA-approved labeling. Thus, this Court has previously granted summary judgment to Wyeth on Plaintiff's "failure to warn claim." It is the precise scope of that ruling which is currently at issue.

Throughout this case Plaintiff has made a variety of allegations against Wyeth and she has asserted claims ranging from negligence to fraud. But as demonstrated below, these allegations amount to nothing more than repackaged failure-to-warn claims, and therefore, they are not viable. At most, Plaintiff's only remaining claim is for strict products liability (design defect) based on the argument that low dose Prempro is a safer alternative design.[1]

II. Nature and Stage of the Proceeding

On May 31, 2012 this Court granted in part Wyeth's Motion for Partial Summary Judgment. The Court found that Texas Civil Practice and Remedies Code Section 82.007's statutory presumption applicable to FDA-approved warnings applies to the hormone therapy medications at issue in this case. The Court further found that Plaintiff could not establish any of the statutory exceptions to the presumption, and therefore, that Wyeth was entitled to summary judgment on failure to warn.

[1] Wyeth continues to dispute the viability of even the design defect claim for the reasons discussed below.

Since the Court's ruling, questions have arisen regarding what claims remain for trial. In addition, recent decisions from the Fifth Circuit and Texas Supreme Court have provided further clarification regarding the Texas law applicable in this case. Therefore, the Court requested that Wyeth file a motion for summary judgment addressing which of Plaintiff's claims remain viable [Doc. No. 169].

III. Statement of Issues and Standard of Review

1. Nearly all of Ms. Romero's claims are based on an alleged failure to warn. Following the Court's summary-judgment ruling, the Fifth Circuit's decision in *Lofton*, and the Texas Supreme Court's decision in *Centocor*, which of Plaintiff's claims remain viable for trial?

2. Does comment k to Section 402A of the Restatement (Second) of Torts bar Ms. Romero's design defect claim?

The standard of review for the grant or denial of summary judgment is de novo. *Templet v. HydroChem Inc.*, 367 F.3d 473, 477 (5th Cir. 2004).

IV. Statement of Undisputed Material Facts

1. Wyeth incorporates by reference its Amended Statement of Undisputed Material Facts filed on March 6, 2012 [Doc. No. 96-1].

2. On May 31, 2012 this Court found that Section 82.007's statutory presumption for FDA-approved warnings applies to the hormone therapy medications prescribed for Plaintiff. In addition, the Court found that Plaintiff had not established any of the exceptions to the presumption.

V. Argument and Authorities

A. The Crux of Plaintiff's Allegations is "Failure to Warn."

Plaintiff's First Amended Petition [sic] contains ten distinct "counts" or causes of action: misrepresentations, fraud and deceit; negligence; negligence *per se*; strict liability for failure to warn; strict liability for defective product (design defect); breach of express warranty; breach of implied warranty; assault and battery; negligent misrepresentation; and deceptive trade practices. Plaintiff stipulated to the dismissal of her negligence *per se*, breach of express

warranty, breach of implied warranty, and assault and battery claims, and therefore, there is no dispute that those claims do not remain for trial. [Doc. No. 77].[2] Accordingly, following the dismissal of these claims, the following claims were the live claims at the time of Wyeth's Motion for Partial Summary Judgment:

- Misrepresentations, fraud and deceit;
- Negligence
- Strict liability for failure to warn;
- Strict liability for defective product (design defect);
- Negligent misrepresentation; and
- Violations of the Texas Deceptive Trade Practices Act

In addition to Plaintiff's claim for strict products liability based on failure to warn—which on its face is precluded by the Court's prior ruling—the remainder of Plaintiff's claims (including portions of her claim for design defect) are based entirely on Wyeth's alleged failure to warn of the breast cancer risk associated with hormone therapy. For example, the factual background applicable to all of Plaintiff's claims alleges that Wyeth "fail[ed] to timely and adequately and appropriately warn" of the risks associated with hormone therapy. Plf.'s First Am. Pet. at ¶ 13; *see also id.* at ¶ 32 (claiming that Wyeth "purposefully and intentionally misled prescribing physicians as to the safety and efficacy" of hormone therapy). In addition, Plaintiff's causes of action for misrepresentations, fraud and deceit, and for violations of the Texas DTPA claim that Wyeth engaged in "misrepresentations" regarding the *risks and benefits* of hormone therapy, that Wyeth "deceived" Plaintiff and made "misrepresentations" regarding the *safety* of hormone therapy, that Wyeth concealed the *risks* of hormone therapy, and that Wyeth's hormone therapy was not "adequately contained, packaged, and labeled." *See id.* at ¶¶ 36, 40, 41, 42, 46, 95, 96, 98.

[2] Plaintiff's First Amended Petition also contains references to the manufacture of Wyeth's hormone therapy medications. To avoid confusion, Plaintiff also stipulated to the dismissal of any purported claim of a manufacturing defect. [Doc. No. 77].

Plaintiff's negligence and negligent misrepresentation causes of action include similar allegations. For instance, Plaintiff's negligence claim alleges that Wyeth "owed a duty to fully and truthfully inform users of the increased risks and adverse effects associated with" hormone therapy. *See id.* at ¶ 52. Plaintiff further alleges that Wyeth did not accompany its hormone therapy products with *proper warnings*, that the "warnings given did not accurately reflect" the side effects, and that Wyeth *failed to warn* Plaintiff or her prescribing physicians. *Id.* at ¶¶ 55, 55(b), 55(c), 55(d), 55(f), 88, 89. Even portions of Plaintiff's claim for strict products liability based on design defect include allegations based on an alleged failure to warn. *See id.* at ¶¶ 78(b), 78(d), 78(e), 78(f) (claiming that Wyeth's hormone therapy medications were defectively designed due to "inadequate warnings or instructions"). In short, Plaintiff's First Amended Petition contains at least twenty-four separate allegations of an alleged failure to warn/inadequate warnings for the FDA-approved hormone therapy prescribed to Plaintiff. These allegations are contained throughout each of Plaintiff's causes of action. *See* Plaintiff's First Amended Petition at ¶¶ 13, 32, 36, 40, 41, 42, 46, 52, 55, 55(b), 55(c), 55(d), 55(f), 78(b), 78(d), 78(e), 78(f), 88, 89, 95, 96, and 98. [Doc. No. 31]. Thus, although Plaintiff's First Amended Petition pleads numerous causes of action, all of these causes of action (with the possible exception of a portion of Romero's design defect claim) are based on one theory—failure to warn.

Although the Court raised a question about whether Plaintiff's negligence claim may be based, in part, on an alleged failure to test, Texas law is clear that such a "claim" is "inexplicably intertwined" with the failure-to-warn allegations. *See Am. Tobacco Co. v. Grinnell*, 951 S.W.2d 420, 437 (Tex. 1997). In *Grinnell*, the decedent's family alleged, in six "interrelated claims," that the decedent started smoking because the cigarette manufacturer did not warn of the potential dangers, and once he began smoking, he could not stop. *Id.* at 425. The Texas

Supreme Court found that the failure to test claim was "inextricably intertwined" with the negligent failure to warn claim, and therefore the failure to test claim must also fail when the negligent warning claim failed. *Id.* at 437. The Court explained that the manufacturer's duty to warn necessarily required testing to ascertain the dangers inherent in the product. *Id.* Therefore, the failure to test claim was not distinct from the negligent failure to warn claim.[3] *Id.*; *see also Dow Agrosciences LLC v. Bates*, 332 F.3d 323, 333 (5th Cir. 2003) ("***[A] negligent testing claims is, as a matter of Texas law, a variation of an action for failure to warn***." (emphasis added)); *Quest Chem. Corp. v. Elam*, 898 S.W.2d 819, 820–21 (Tex. 1995) (dismissing plaintiff's negligent testing claim because it was "based solely upon Quest's alleged failure to provide adequate warnings and instructions on its product" and therefore subsumed within plaintiff's failure to warn claim);[4] *Kociemba v. G.D. Searle & Co.*, 707 F. Supp. 1517, 1527 (D.

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[3] Moreover, before FDA can approve a new drug application it must find that "adequate tests by all methods reasonably applicable" have been done. 21 U.S.C. § 355(d); *Bailey v. Wyeth, Inc.*, 37 A.3d 549, (N.J. Sup. Ct. 2008), aff'd *Deboard v. Wyeth, Inc.*, 28 A.3d 1245 (N.J. App. Div. 2011) (granting summary judgment for Wyeth on nearly identical claims to those brought in this case and recognizing that when considering a drug for approval, the FDA must determine that the scientific evidence is adequate to show that a product is safe and effective and that "if the FDA concludes that there has not been sufficient study of the product . . . FDA will reject" approval of the drug). The *Bailey* opinion contains a detailed discussion of FDA's multiple advisory committee meetings addressing hormone therapy and FDA's decisions with regard to the hormone therapy labeling over the years. The advisory committee regularly discussed the risk of breast cancer at its meetings and FDA ultimately approved hormone therapy and the breast cancer warning contained in the labeling on multiple occasions. *Bailey*, 37 A.3d at 559-69. The *Bailey* court ultimately concluded that "[t]he FDA has been actively involved in the labeling and monitoring of [hormone therapy] for several decades." *Id.* at 577.

[4] Wyeth acknowledges that this case was decided prior to the Supreme Court's decision in *Wyeth v. Levine*, 555 U.S. 555 (2009). However, the Supreme Court's decision regarding preemption does not change the *Quest* court's finding that the negligent testing claim was based solely on the alleged failure to warn. Additionally, Wyeth is aware of one Texas Court of Appeals decision recognizing a distinction between negligent failure to warn and negligent failure to test. *See Sico N. Am., Inc. v. Willis*, No. 14-08-00158-CV, 2009 Tex. App. LEXIS 7239, at * 25 (Tex. App.—Houston [14th Dist.] Sept. 10, 2009, no pet.). However, that case is inapplicable here for several reasons. First, it did not involve FDA-approved prescription

Minn. 1989) (explaining that the duty to test is a subpart of the duty to provide adequate warnings).

The same is true in this case where Plaintiff claims that Wyeth did not "conduct adequate . . . testing . . . to ***determine the safety***" of hormone therapy. Plf.'s First Am. Pet. ¶ 55(d) (emphasis added) [Doc. No. 31]. Plaintiff does not claim that Wyeth's hormone therapy medications failed to include any breast cancer warning at all due to a lack of testing. Rather, she claims that the warning would have come sooner and been stronger had additional tests been done. *See* Joint Pretrial Order at p. 4, 6 [Doc. No. 167] (contending that Wyeth failed to adequately test hormone therapy so that it "could convey adequate and accurate risk information" and that after the Women's Health Initiative study the "wishy-washy" warning about breast cancer was replaced by a more "definitive" warning). In other words, the breast cancer warning was not strong enough (i.e., ***it was not adequate***) because Wyeth did not test. This argument is clearly "inextricably intertwined" with the failure-to-warn allegations, and therefore, cannot be the basis of a separate cause of action.

Because the vast majority of Plaintiff's claims rest on an alleged failure to warn, Wyeth moved for summary judgment on all of Plaintiff's "claims based on an alleged failure to warn." Wyeth's Mot. for Partial Summ. J. at p. 1 of 31 "Wyeth's Motion" [Doc. No. 90]. On May 31, 2012, this Court found that Plaintiff could not rebut the statutory presumption for FDA-approved warnings, and therefore concluded that Wyeth was entitled to summary judgment on the issue of failure to warn. Memorandum and Order at 15 [Doc. No. 146]. Accordingly, it is Wyeth's

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medications where the plaintiff claims that the defendants tests were insufficient. Second, the plaintiff alleged a malfunction with a lock bar and claimed at trial that the defendant did not conduct *any testing* on the lock bar at all. In this case Plaintiff's claim is simply that Wyeth did not do *enough testing* regarding the *known risk* of breast cancer associated with hormone therapy. And third, the defendant did not object to the introduction of a failure to test issue or its submission to the jury.

contention that all of Plaintiff's claims based on an alleged failure to warn are no longer valid pending claims in this case. At most, Plaintiff is left with only a strict liability claim for design defect based on the argument that low dose Prempro is a safer alternative design.[5] However, Wyeth continues to dispute the viability of this claim because the Restatement (Second) of Torts Section 402A, comment k applies to preclude a design defect claim in a prescription drug case where, as here, the FDA-approved warnings are adequate as a matter of law.[6]

B. The Statutory Presumption Applicable to FDA-Approved Warnings is Dispositive of all Claims Based on an Alleged Failure to Warn.

i. The statutory presumption applies to all claims based on "failure to warn" or alleged inadequate warnings.

Texas Civil Practice and Remedies Code Section 82.007 provides a statutory presumption that a manufacturer is not liable for an alleged failure to warn when the labeling at issue was approved by FDA. Section 82.007's presumption for FDA-approved warnings applies in any "products liability action" based on an alleged failure to warn. According to Section 82.001(2), a products liability action is "any action against a manufacturer or seller for recovery of damages arising out of personal injury, death, or property damage allegedly caused by a defective product

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[5] Plaintiff's First Amended Petition also includes a claim of negligent design. Such a claim is subsumed within a design defect claim. *Kia Motors Corp. v. Ruiz*, 348 S.W.3d 465, 476 (Tex.App.—Dallas 2011, pet. pending) ("Normally, strict products liability and negligence are separate causes of action with different elements. . . . Here, however, because the only negligence Ruiz alleged related to the design of the product, the negligence theories were subsumed and encompassed in the defective product theory, and Ruiz's burden at trial was to prove injury resulting from defective design."). *See also* Texas PJC 71.4 "**Note on submitting strict liability, negligence, or implied warranty in the same case.** When the controlling issue regarding the existence of a defect for strict liability, negligence, or implied warranty are functionally identical, 'a trial court is not required to, and should not confuse the jury by submitting differently worded questions that call for the same factual finding.'"

[6] In addition, Wyeth disputes the viability of the design defect claim because Plaintiff's summary-judgment response contained no evidence to raise any issue of material fact as to the existence of a safer alternative design. *See Plaintiff's Opposition to Wyeth's Motion for Partial Summary Judgment* at 38-40 [Doc. No. 110]; *Wyeth's Reply Brief in Support of Motion for Partial Summary Judgment* at 5-6 [Doc. No. 122].

whether the action is based in strict tort liability, strict products liability, negligence, misrepresentation, breach of express or implied warranty, or any other theory or combination of theories." (emphasis added).

Within the last six weeks the Southern District of Texas granted a motion to dismiss several causes of action based on the statutory presumption. *Valle v. Qualitest Pharm. Inc.*, No. B-11-113, 2012 U.S. Dist. Lexis 100798, at *10 (S.D. Tex. June 22, 2012) (Hanen, J.). According to the court, the "presumption of no liability applies regardless of how the cause of action is framed as the definition of 'Products liability action' is a broadly crafted term under Texas law." *Id.* at *4. Like Ms. Romero in this case, the plaintiff in *Valle* brought a number of different causes of action against the defendant. *Id.* at *5. But also like Ms. Romero, the plaintiff in *Valle* primarily sought damages based on an alleged failure to warn/inadequate warning. *Id.* at *6. Thus, the court rejected the plaintiff's argument that some of her claims should survive, stating "Texas law groups all inadequate warning causes of action together regardless of how they are pleaded. If the claim is based upon the labeling, its omissions, or inaccuracies, it falls under this purview of the above-quoted Texas Civil Practice and Remedies Code provisions." *Id.*; *see also Murthy v. Abbott Labs.*, No. 4:11-cv-105, 2012 U.S. Dist. Lexis 29683, at *43-*44 (S.D. Tex. Mar. 6, 2012) (Ellison, J.) ("As Murthy's strict liability and breach of warranty claims are premised on failure to warn, they must be dismissed pursuant to Section 82.007(a)."), at *38 ("Section 82.007 applies to all products liability actions alleging that an injury was caused by a failure to provide adequate warnings or information with regard to a pharmaceutical product."); *Eckhardt v. Qualitest Pharms. Inc.*, No. M-11-235, 2012 U.S. Dist. Lexis 62202, at *11, *15 (S.D. Tex. Apr. 30, 2012) (Alvarez, J.) (noting "that despite the multiple claims asserted by Plaintiffs, this is essentially a products liability case, with the claim

arising from a failure to warn" and that because the statutory presumption applied, "Plaintiffs cannot prevail on any failure to warn theory").

Here, there can be no question that this is a "products liability action" within the definition of the statute. Moreover, as discussed above, the primary basis for all of Plaintiff's claims (except for a portion of her design defect claim) is that Wyeth failed to adequately warn about the risks associated with hormone therapy. *See supra* Section V.A. Therefore, the statutory presumption applies, and is dispositive, of all of Plaintiff's claims based on an alleged failure to warn.

ii. When the statutory presumption applies, the FDA-approved warning is presumed adequate.

A finding that the statutory presumption applies and has not been rebutted is the equivalent of a finding that the FDA-approved labeling is ***adequate as a matter of law***. *See Thurston v. Merck & Co.*, 415 F. App'x 585, 586 (5th Cir. 2011) ("***Texas law provides that an FDA-approved warning is presumed to be an adequate warning***." (emphasis added)), *cert denied*, 2011 U.S. Dist. Lexis 6184 (U.S. Oct. 3, 2011); *Ebel v. Eli Lilly Co.*, 536 F. Supp. 2d 767, 774 (S.D. Tex. 2008) ("Under Texas law, Food and Drug Administration approval of a pharmaceutical medicine creates a rebuttable presumption that the approved warning is adequate."); *Holland v. Hoffman-La Roche, Inc.*, No. 3:06-cv-1298-bd, 2007 U.S. Dist. Lexis 84507, at *8 (N.D. Tex. Nov. 15, 2007) (after finding that statutory presumption applied to the warnings, stating "[p]rescription drugs are not susceptible to a design defect claim where, as here, the drug is 'accompanied by proper directions and warning'" (internal citation omitted)).

In *Ebel v. Eli Lilly & Co.*, the plaintiff sued Eli Lilly & Company after the decedent committed suicide while he was taking one of the Eli Lilly's prescription medications. 536 F. Supp. 2d 767, 770 (S.D. Tex. 2008). The plaintiff brought three causes of action against Eli

Lilly—strict liability, negligence, and breach of warranty—all of which were based on a failure to warn. *Id.* at 770-71. The defendant moved for summary judgment based on the learned intermediary doctrine and based on the statutory presumption applicable to FDA-approved warnings. *Id.* at 772-73.

In granting summary judgment for the defendant on all claims, the court found that Section 82.007's presumption applicable to FDA-approved warnings applied to the prescription medication taken by the decedent and that this meant that the warnings were adequate as a matter of law. *Id.* at 774. The court recognized: "Under Texas law, that FDA approval creates a rebuttable presumption ***that the approved warning is adequate***." *Id.* (emphasis added) (citing TEX. CIV. PRAC. & REM. CODE ANN. § 82.007(a) and *Holland v. Hoffman-La Roche, Inc.*, *slip op.*, 2007 U.S. Dist. Lexis 84507, at *6, 2007 WL 4042757, at *2 (N.D. Tex. 2007). The court further stated: "As Plaintiff has not met her burden of rebutting the presumption, ***Defendant need not provide further evidence that the label is adequate***." *Ebel*, 536 F. Supp. 2d at 775 (emphasis added) (internal citation omitted); *id.* at 778 (noting that Eli Lilly's labeling was presumed adequate); *id.* at 780-81 ("As explained above, the FDA approved the warning labels Defendant provided for Zyprexa. ***Therefore, this Court may presume that the warning was adequate***." (emphasis added)).

Once the court finds that the presumption applies and has not been rebutted, it is fundamentally inconsistent with the purpose of Section 82.007's presumption to allow Plaintiff to argue to a jury that the FDA-approved warnings accompanying the hormone therapy medications prescribed to Plaintiff were inadequate. This would result in Wyeth being put in the very position that Section 82.007's presumption seeks to avoid—the position of litigating the issue of the warnings' adequacy over and over again when those warnings have already been

approved by FDA. *See Ebel*, 536 F. Supp. 2d at 775 (finding that because the statutory presumption applied, "***Defendant need not provide further evidence that the label is adequate***." (emphasis added)). Because the statutory presumption applies in this case and has not been rebutted, Wyeth's FDA-approved labeling for Premphase and Prempro are adequate as a matter of law and all of Plaintiff's claims based on an alleged inadequate warning are extinguished. This includes all of Plaintiff's claims except her strict liability (design defect) claim based on the argument that low dose Prempro is a safer alternative design.

iii. The Fifth Circuit's decision in *Lofton* confirms that plaintiffs may not rely on the fraud-on-the-FDA exception to the statutory presumption unless FDA itself has found fraud.

On February 22, 2012, the Fifth Circuit affirmed United States District Judge Sam Lindsay's opinion granting summary judgment for a pharmaceutical manufacturer on the plaintiffs' marketing defect (failure to warn), breach of express warranty, negligence, and DTPA claims. *See Lofton v. McNeil Consumer & Specialty Pharm.*, 672 F.3d 372, 373 (5th Cir. 2012) ("*Lofton II*"), aff'g *Lofton v. McNeil Consumer & Specialty Pharm.*, 682 F. Supp. 2d 662, 681 (N.D. Tex. 2010) ("*Lofton I*"). Judge Lindsay granted summary judgment on these claims after finding that they were premised on a failure to warn and that Section 82.007's presumption for FDA-approved warnings applied, leaving "***no genuine issue of material fact whether Defendants' Motrin label in 2000 was adequate . . . .***" *Lofton I*, 682 F. Supp. 2d at 675 (emphasis added).

In *Lofton I*, the plaintiffs "brought claims of defective design,[7] marketing defect, breach

[7] Judge Lindsay declined to apply comment k to the plaintiffs' design defect claim, but only because the cases adopting comment k to such claims dealt with prescription medications instead of over-the-counter drugs. The *Lofton* case dealt with over-the-counter Motrin. *Lofton I*, 682 F. Fupp. 2d at 665. In addition, after Judge Lindsay's summary-judgment ruling, the defendants filed a supplemental motion for summary judgment seeking dismissal

of express warranty, breach of implied warranty, negligence, and a violation of the Texas Deceptive Trade Practices Act . . . ." *Id.* at 665. Nearly all of these claims, however, were based on an alleged failure to warn of the risks associated with over-the-counter Motrin. *Id.* at 672. The defendants argued that under Section 82.007's presumption, the Motrin warning label was "presumptively adequate." *Id.* at 673. Judge Lindsay agreed, and after finding that the fraud-on-the-FDA exception to the presumption was preempted, granted summary judgment on the warnings-related claims. *Id.* at 681. In affirming Judge Lindsay on appeal, the Fifth Circuit specifically recognized that Section 82.007 "presumptively insulates from liability, for failure to warn, defendants who made, prescribe, or sell drugs in accord with FDA standards." *Lofton II*, 672 F.3d at 379.

Prior to the *Lofton* decisions it was clear that when the statutory presumption applies and has not been rebutted, the warnings are presumed adequate as a matter of law. *See, e.g.*, *Thurston*, 415 Fed. Appx. 585 ("Texas law provides that an FDA-approved warning is presumed to be an adequate warning."); *Ebel*, 536 F. Supp. 2d at 774 ("Under Texas law, Food and Drug Administration approval of a pharmaceutical medicine creates a rebuttable presumption that the approved warning is adequate."); *Holland*, 2007 U.S. Dist. Lexis 84507, at *8 (after finding that the statutory presumption applied to the warnings, stating "[p]rescription drugs are not susceptible to a design defect claim where, as here, the drug is 'accompanied by proper directions and warning'" (internal citation omitted)).

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of the plaintiffs' remaining claims, including design defect. *See Lofton I*, Case No. 3:05-cv-1531-l (N.D. Tex.) [Doc. No. 127, 128]. On August 20, 2010, plaintiffs conceded the dismissal of their remaining claims, stating specifically that "Plaintiffs cannot prove a defective design case by saying that the Defendant should have sold a different drug." [Doc. No. 130, 131].

In *Lofton II*, the Fifth Circuit answered the question of whether plaintiffs could continue to rely on the fraud-on-the-FDA exception to the presumption in light of the Supreme Court's decision in *Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). According to the Fifth Circuit, the answer is "no" unless the FDA itself has found fraud. As a result, in situations involving an FDA-approved label where the FDA has not found that it was defrauded by the manufacturer, the warnings are presumed adequate unless the plaintiff can establish one of the remaining statutory exceptions, most often the "overpromotion" exception. Moreover, the *Lofton* decisions implicitly state what the Texas Supreme Court would make clear in *Centocor*: when the gravamen of the plaintiff's allegations are an alleged failure to warn, the plaintiff cannot plead around the requirements of a strict products liability failure-to-warn claim by bringing common law causes of action.

C. A Prescription Drug Manufacturer Fulfills The Duty to Warn by Providing an Adequate Warning to the Prescribing Physician.

On June 8, 2012 the Texas Supreme Court confirmed that "a prescription drug manufacturer fulfills its duty to warn its product's end users by providing an adequate warning to the prescribing physician." *Centocor, Inc. v. Hamilton*, No. 10-0223, 2012 Tex. LEXIS 463, 55 Tex. Sup. J. 774 (Tex. June 8, 2012) ("*Centocor II*").

In *Centocor*, Patricia Hamilton and her husband sued drug manufacturer Centocor, Inc., alleging that Ms. Hamilton developed a lupus-like syndrome from her use of the prescription drug Remicade. *Id.* at *4-6. Remicade's package insert warned that one of the risks of use was the development of a lupus-like syndrome.[8] *Id.* at *10-12. Because Remicade is administered intravenously, Hamilton's doctor referred her to an infusion clinic to receive the infusions. *Id.* at

[8] The Hamiltons sued Centocor in March, 2003, and therefore, the statutory presumption for FDA-approved warnings did not apply. *See Centocor II*, 2012 Tex. Lexis 463, at *59 n. 19.

*14-15. While Hamilton received her first infusion, she watched a video produced by Centocor that discussed the beneficial effects of Remicade. *Id.* at *15-19. Hamilton alleged that the video over-emphasized the benefits of Remicade and intentionally omitted a warning about a lupus-like syndrome. *Id.* at *4-5. The jury found Centocor liable for fraud, negligent misbranding, negligent marketing to Hamilton's doctors, misrepresentation to Hamilton's doctors, and negligent undertaking. *Id.* at *27-28. The trial court entered judgment against Centocor on the fraud claim and awarded approximately $4.8 million in actual and punitive damages to Hamilton and her husband. *Id*.

On appeal, Centocor argued that the learned intermediary doctrine precluded the Hamiltons' claims. *Centocor, Inc. v. Hamilton*, 310 S.W.3d 476, 481 (Tex. App.—Corpus Christi 2010) ("*Centocor I*"). Centocor asserted that because it had adequately warned Hamilton's physicians of the risk of developing a lupus-like syndrome, it had no duty to warn Hamilton directly. *Id.* at 499. The Corpus Christi Court of Appeals disagreed, recognizing for the first time in Texas a direct-to-consumer ("DTC") advertising exception to the learned intermediary doctrine. *Id.* at 507-08. The court affirmed the judgment for the Hamiltons, holding that the doctrine does not apply "when a drug manufacturer engages in DTC advertising that fraudulently touts the drug's efficacy while failing to warn of the risks." *Id.* at 522.

The Supreme Court of Texas granted Centocor's petition for review and reversed and rendered judgment for Centocor based on the learned intermediary doctrine. *Centocor II*, 2012 Tex. Lexis 463, at *33-35. Although the Court had never addressed whether the learned intermediary doctrine applies in the prescription drug context, the Court confirmed that "a prescription drug manufacturer fulfills its duty to warn its product's end users by providing an adequate warning to the prescribing physician." *Id.* at *47-48. The Court then held that the

court of appeals erred in recognizing a direct-to-consumer advertising exception to the learned intermediary doctrine. *Id.* at *62-69. The Court noted that despite the fact that direct-to-consumer advertising has increased since the adoption of the learned intermediary doctrine, "the fundamental rationale for the doctrine remains the same: prescription drugs require a doctor's prescription and, therefore, doctors are best suited to communicate the risks and benefits of prescription medications for particular patients through their face-to-face interactions with those patients." *Id.* at *68-69. Moreover, both federal and Texas law regulate the design, marketing, and distribution of prescription drugs, and the Court observed that this regulation protects the public from harmful products and misleading advertising. *Id.* at *62-63 & n. 24.

After concluding that there was no exception to the learned intermediary doctrine in this case, the court then determined that the doctrine applied to all of Hamilton's claims. *Id.* at *80-86. Even though the Hamiltons (like Ms. Romero) brought several common law claims, including fraud, the court concluded ***that each of the claims rested on Centocor's alleged failure to provide an adequate warning, and that a plaintiff cannot plead around the basic requirements of a failure-to-warn claim***. *Id.* at *84-85. *See also id.* at *84-*85 ("[T]he Hamiltons' fraud-by-omission claim is premised solely on its allegation that Centocor knowingly omitted material facts about Remicade's potential to cause lupus-like syndrome."); *see also In re Norplant*, 955 F. Supp. 700, 709 (E.D. Tex. 1997) ("The gravamen of all of Plaintiffs' causes of action, including misrepresentation and violation of the DTPA, is that [the prescription drug manufacturer] failed to adequately warn of or disclose the severity of Norplant's side effects" and "If the [learned intermediary] doctrine could be avoided by casting what is essentially a failure to warn claim under a different cause of action such as violation of the DTPA or a claim for misrepresentation, then the doctrine would be rendered meaningless.").

The court also rejected the plaintiffs' argument that Centocor's "multi-pronged marketing strategy" had any bearing on plaintiffs' claims because Ms. Hamilton received information about Remicade from her prescribing physician. *Centocor II*, 2012 Tex. Lexis 463, at *67-68 n.25. Finally, the court held that the learned intermediary doctrine is not an affirmative defense, explaining that "[w]hile the learned intermediary doctrine shifts the manufacturer's duty to warn the end user to the intermediary, it does not shift the plaintiff's basic burden of proof." *Id.* at *74.

The *Centocor* decision makes at least two things clear in this case. First, despite the fact that Ms. Romero (like the Hamiltons) has pleaded several causes of action against Wyeth, her claims are all based on an alleged failure to warn/inadequate warning (the only exception being the design defect claim based on low dose Prempro). The learned intermediary doctrine is applicable to the claims based on the alleged failure to warn. In addition, the statutory presumption for FDA-approved warning labels is also applicable. Ms. Romero cannot plead around either of these issues of law, both of which are fatal to her claims.

Second, although Ms. Romero's previous summary-judgment response put forth a barrage of internal marketing documents in an attempt to survive summary judgment, what matters here is that FDA approved the labeling at issue in this case. Plaintiff's reliance on marketing-related documents, including ones that neither she nor her prescribing physicians have ever seen is insufficient to allow any of her claims to proceed to trial. The reason is simple: Plaintiff's allegations regarding Wyeth's marketing campaign are nothing more than additional arguments in support of her claim that Wyeth did not adequately warn of the risk of breast cancer associated with hormone therapy.

D. Comment K Precludes Plaintiff's Design Defect Claim.

The Court has previously raised the question of the applicability of comment k to the Restatement (Second) of Torts Section 402A, expressing concern that even if comment k barred all design defect claims in the case of prescription medicines, comment k still emphasizes the necessity of appropriate warnings. For purposes of this motion, however, the Court need not decide if comment k is universally applicable to all design defect cases involving prescription medications because the specific facts of this case necessitate the application of comment k.

In its Memorandum and Order on May 30, 2012, the Court held that Plaintiff's experts presented evidence calling into question the adequacy of the warnings accompanying Premphase and Prempro, and therefore, that Plaintiff's design defect claim was not precluded by comment k. But this is fundamentally at odds with the Court's finding that the statutory presumption applies to the warnings. As discussed, the warnings in this case are deemed adequate as a matter of law, and Wyeth "need not provide further evidence that the label is adequate." *Ebel*, 536 F. Supp. 2d at 775. In other words, because the warnings are adequate as a matter of law, Plaintiff cannot raise a genuine issue of material fact as to the adequacy of the warnings under comment k.

Magistrate Judge Jeff Kaplan of the United States District Court for the Northern District of Texas recognized this issue when he granted summary judgment for the defendants in a case involving claims based on failure to warn and design defect. *See Holland v. Hoffman-La Roche, Inc.*, No. 3:06-cv-1298-bd, 2007 U.S. Dist. Lexis 84507, at *9 (N.D. Tex. Nov. 15, 2007). In *Holland*, the court first found that the statutory presumption for FDA-approved warnings applied. Because the plaintiff did not present any evidence to rebut the presumption, the court found that summary judgment was appropriate as to the plaintiff's failure-to-warn claim. *Id.* at *8. The court further held that there was no triable issue with respect to the design defect claim

because (based on the statutory presumption) "the drug [was] 'accompanied by proper directions and warning.'" *Id.* (internal citation omitted). *See also Hackett v. G.D. Searle & Co.*, 246 F. Supp. 2d 591, 595 (W.D. Tex. 2002) (finding that comment k bars design defect claims involving prescription medications because allowing such a claim "would provide a disincentive to companies to develop new drugs and would allow juries to second-guess the FDA's approval of the drugs for marketing"); *Gerber v. Hoffman-La Roche, Inc.*, 392 F. Supp. 2d 907, (S.D. Tex. May 20, 2005) (finding that the warning was adequate[9] and that comment k precluded the assertion of a design defect claim); *Dusek v. Pfizer Inc.*, No. H-02-3559, 2004 U.S. Dist. Lexis 28049, at *6 n.1 (S.D. Tex. Nov. 22, 2004) (noting that comment k "provides that a plaintiff may not bring a design-defect claim for prescription medication"); *Massa v. Genentech Inc.*, No. H-11-70, 2012 U.S. Dist. Lexis 36465, at *14 (S.D. Tex. Mar. 19, 2012) (noting that under comment k, "a prescription drug is unreasonably dangerous in design if it ***is not 'accompanied by proper directions and warning***'" (emphasis added)).

Texas law is clear that comment k applies to prescription drug design defect claims. Once applicable, comment k precludes a design defect claim so long as there is an adequate warning. In this case, the Court has already found that the statutory presumption applies to Wyeth's hormone therapy medications and that Plaintiff has no evidence to rebut the presumption. Therefore, the warnings are deemed adequate as a matter of law. Even if the Court is not inclined to find that comment k bars all design defect claims in cases involving prescription medications, comment k still precludes Plaintiff's design defect claim in this case.

[9] The *Gerber* case was filed prior to the effective date of Section 82.007, and therefore, the Court determined the adequacy of the warning without the benefit of the statutory presumption.

VI. Conclusion

The crux of Plaintiff's allegations against Wyeth is an alleged failure to adequately warn of the risks associated with hormone therapy. This Court has already found that the statutory presumption for FDA-approved warnings applies and has not been rebutted in this case. Texas law is clear that when this presumption applies, the warnings are deemed adequate as a matter of law. Therefore, the statutory presumption is dispositive of all of Plaintiff's claims based on an alleged failure to warn: misrepresentations, fraud and deceit; negligence; strict products liability (failure to warn); negligent misrepresentation, and violations of the Texas Deceptive Trade Practices Act. Accordingly, at most Plaintiff has only a strict products liability claim for design defect based on the argument that low dose Prempro was a safer alternative design. But based on comment k, Wyeth maintains that even Plaintiff's design defect claim should be dismissed.[10]

Dated: August 6, 2012

[10] Wyeth also continues to question the validity of any design defect claim because Plaintiff's summary-judgment response put forth no evidence raising an issue of fact as to any of the elements of safer alternative design. *See Plaintiff's Opposition to Wyeth's Motion for Partial Summary Judgment* at 38-40 [Doc. No. 110]; *see also Order Granting Motion to Exclude Safer Alternative Design Testimony of Drs. Tilley and Austin* at 10-11 [Doc. No. 128] (excluding testimony that E+OMP is a safer alternative design).

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 6th day of August, 2012 a true and correct copy of the foregoing was filed with the Court and served via electronic notification on all counsel of record.

/s/ Janelle L. Davis
Janelle L. Davis

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